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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 09/738,612 | 12/15/2000 | Peter J. Costa | MDS-020 | 2198 |
| 21323 | 7590 | 02/05/2004 | EXAMINER | |
| TESTA, HURWITZ & THIBEAULT, LLP | | | NGHIEM, MICHAEL P | |
| HIGH STREET TOWER | | | ART UNIT | |
| 125 HIGH STREET | | | PAPER NUMBER | |
| BOSTON, MA 02110 | | | 2863 | |

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AK

Office Action Summary

Applicati n No.

09/738,612

Applicant(s)

COSTA ET AL.

Examiner

Michael P Nghiem

Art Unit

2863

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9-11 and 19 is/are rejected.
- 7) ☒ Claim(s) 2-8,12-18,20 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7-22-03,10-6-03,11-i 4-03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed on September 2, 2003 has been acknowledged.

Information Disclosure Statement

1. The information disclosure statement filed on July 22, 2003 (9 sheets) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The C4 and C5 references, T. Wilson "The Role of the Pinhole in Confocal Imaging Systems" and C. Koester "Comparison of Optical Sectioning Methods: The Scanning Slit Confocal Microscope", filed on July 22, 2003, have not been considered because they lack publication dates.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 9-11, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Nordstrom et al. (US 6,427,082).

Nordstrom et al. discloses all the claimed features of the invention including:

- a method of performing spectral analysis (Fig. 1), said method comprising:
 - obtaining an optical spectrum (column 4, lines 34-46), and normalizing said optical spectrum by application of non-uniform segment normalization (column 7, lines 6-22);
 - obtaining said spectrum from a specimen of human cervical tissue (Abstract, lines 1-2, Fig. 1);
 - determining a disease status of said test specimen by analyzing said optical spectrum subsequent to said normalizing (column 2, lines 13-17);
- a system (Fig. 1) for performing spectral analysis comprising:
 - a spectrographic device (1), adapted to obtain an optical spectrum from a test specimen (5),
 - a processor (12) adapted to normalize said optical spectrum by application of non-uniform segment normalization (Fig. 8);

- said spectrographic device is further adapted to obtain said optical spectrum from a specimen of human cervical tissue (Abstract, lines 1, 2, Fig. 1).

Allowable Subject Matter

3. Claims 2-8, 12-18, 20, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

4. Applicant's arguments filed September 2, 2003 have been fully considered but they are not persuasive.

With respect to the 35 USC 102 rejections, Applicants argue that Nordstrom does not describe normalizing an optical spectrum by application of non-uniform segment normalization.

Examiner's position is that Nordstrom discloses normalizing an optical spectrum (Fig. 4) by application of non-uniform segment normalization (column 7, lines 6-22). Fig. 4 shows two non-uniform spectrum segments (Average Normalized Spectrum vs. Average CIN II/III Normalized Spectrum) being plotted against each other. Each spectrum is normalized by dividing each spectrum by the total area under the fluorescence spectrum from 390nm to 620 nm.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

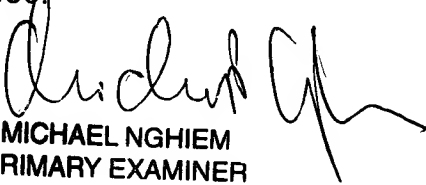
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Nghiem whose telephone number is (703) 306-3445. The examiner can normally be reached on M-H from 6:30AM – 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached at (703) 308-3126. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7724 for regular communications and (703) 308-5841 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

0956.



MICHAEL NGHIEM
PRIMARY EXAMINER

Michael Nghiem

February 2, 2004